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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,238	10/31/2003	Min Wan	2000.615 USD1	2367

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,238	WAN ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-32 and 37-39* is/are rejected.

7)☒ Claim(s) *33-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' species/subgenus elections are acknowledged:

a) the specific peptide present is SEQ ID NO: 1;

b) in the elected method, a filter press is utilized;

c) the protein is expressed in *E. Coli*;

d) the proteins are not purified;

Claims 24-39 remain pending.

Claims 24-25 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of USP 6,995,246. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

✧

Claims 24-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 24 of copending application Serial No. 10/698230. Although the conflicting claims are not identical, they are not patentably distinct from each other. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed

terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)

✧

Claim 35 is objected to. The method ... wherein the lysate **is a comprises...**"

This contains an obvious typographical/grammatical error.

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 24-32 and 37-39 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371).

Hsu discloses a method for obtaining KGF from lysed bacteria which expressed the KGF. Cell lysis is also disclosed (e.g., col 11, line 10+). Hsu also discloses (col 12, line

25+) removal of endotoxins. Also disclosed (col 11, line 19) is the use of a "filter aid" to clarify the cell lysate. Also disclosed (e.g., col 2, line 56+) is blocking of cysteine sulfhydryl groups.

Hennan discloses (col 10, line 41) that diatomaceous earth is useful for preventing clogging of filters when filtering protein solutions that contain precipitates. Hennan does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins.

Colpan discloses a method for removal of cellular debris comprising a filtration step. A preferred filtration aid (col 2, line 31+) is diatomaceous earth. Colpan does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins.

Thus, a practioner of the Hsu invention would purify KGF from lysed bacteria by using various methods including a filtration aid. Hsu discloses the claimed invention, except that there is no specific teaching that the "filter aid" should be diatomaceous earth. However, a protein chemist in possession of Colpan or Hennan would have recognized that if a filter aid is used, diatomaceous earth would have been effective for this purpose.

Consider next claims 37-39. As it happens, the limitations in these claims are meaningless, because the claims specify the yield of solution, rather than the yield of protein. Suppose that a protein chemist is endeavoring to purify a protein, either by the

claimed method, or by some unrelated method. Let the protein of interest be designated as "protein X". Suppose that the chemist has 100 mL of a solution that contains 5 g of protein, together with some lipid and inorganic salts. Of the initial 5 g of protein, suppose that 1 gram is protein X. And suppose that the chemist then proceeds to purify protein X by a multistep process, at the end of which he has only 100 mg of the original 1 gram of protein X. Thus, for most practical purposes, one would say that his yield was 10%. But by applicants criteria, the "yield" could easily be 100%, or even more than 100%. The reason is that, according to applicants, the amount of protein that is recovered is largely irrelevant; what matters to applicants is the volume of solution in which the protein is dissolved. So in this example, if the chemist took his 100 mg of final product (which represents, as indicated, a 10% yield), and dissolved that in 100 mL of water, the "yield of solution" would suddenly rise to 100%. Thus, to characterize a yield only in terms of volume of solution is not meaningful.

Thus, the claims are rendered obvious.

✦

Claims 24-32 and 37-39 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Bobbitt (USP 4923967) further in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371).

The teachings of Hsu, Hennen and Colpan are indicated above. None of these discloses use of sodium thiosulfate or sodium tetrathionate. Bobbitt discloses (col 3, line 27) a process which comprises sulfitolysis; the sulfitolysis may be achieved (col 5, lin 24) by use of sodium thiosulfate or sodium tetrathionate.

Thus, the claims are rendered obvious.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER